



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

De Novo Classification Process (Evaluation of Automatic Class III Designation); Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “De Novo Classification Process (Evaluation of Automatic Class III Designation).” The purpose of this document is to provide FDA’s proposals for guidance to FDA staff and industry on the process for the submission and review of petitions submitted under the Evaluation of Automatic Class III Designation section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), also known as the de novo classification process. FDA is issuing this draft guidance to provide proposed updated recommendations for efficient interaction with FDA, including what information to submit when seeking a path to market for a novel device via the de novo process. This draft guidance has been revised and is being reissued for comment because the Food and Drug Administration Safety and Innovation Act (FDASIA), which became law on July 9, 2012, amended the FD&C Act to provide for the submission of de novos without a preceding premarket notification (510(k)) submission. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “De Novo Classification Process (Evaluation of Automatic Class III Designation)” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993-0002, 301-796-5616, melissa.burns@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

A medical device that is of a new type that FDA has not yet classified, and therefore cannot be found to be substantially equivalent to a legally marketed predicate device, is “automatically” or “statutorily” classified into class III by operation of section 513(f)(1) of the FD&C Act (21 U.S.C. 360c(f)(1)) even if the risks it presents are relatively low. This is the scenario contemplated by Congress when it enacted section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)) as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision is referred to in FDAMA as the Evaluation of Automatic Class III Designation (e.g., the de novo process). Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if lower risk devices were subject to premarket approval under section 515 of the FD&C Act (21 U.S.C. 360e).

Section 513(f)(2) of the FD&C Act was amended again by Congress under section 607 of FDASIA (Public Law 112-144) in 2012. Section 513(f)(2) provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, after receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no

legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act.

On October 3, 2011, FDA published a notice of availability of a draft guidance document on the de novo classification process (76 FR 61103). The comment period closed on December 2, 2011. After the passage of FDASIA in 2012 added a procedure by which a person may request FDA to classify a device under 513(f)(2) of the FD&C Act, FDA decided it should revise the 2011 draft guidance to include recommendations regarding the second procedure.

Accordingly, FDA is issuing this draft guidance to provide updated proposed recommendations designed to foster efficient interaction with FDA, including what information to submit, when seeking a path to market via the de novo process. This draft guidance describes a proposed mechanism to provide greater clarity about the process for de novo review and the type of data necessary to support de novo classification of an eligible device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the de novo classification process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default>

[t.htm](http://www.regulations.gov). Guidance documents are also available at <http://www.regulations.gov> or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of “De Novo Classification Process (Evaluation of Automatic Class III Designation)” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1769 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501-3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c) (2)(A) of the PRA (44 U.S.C. 3506 (c) (2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry and Food and Drug Administration Staff: De Novo Classification Process (Evaluation of Automatic Class III Designation)

This draft guidance describes how CDRH and CBER intend to implement section 513(f)(2) of the FD&C Act. Section 513(f)(2) provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure (section 513(f)(2)(i)), the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, after receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure (section 513(f)(2)(ii) of the FD&C Act), rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. When final, this document will supersede “New Section 513(f)(2)--Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff” dated February 19, 1998.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Submission of Information for De Novo Classification Program	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Respondent (in hours)	Total Hours
CDRH (21 U.S.C. 513(f)(2)(i))	25	1	25	100	2,500
CBER (21 U.S.C. 513(f)(2)(i))	1	1	1	100	100
CDRH (21 U.S.C. 513(f)(2)(ii))	25	1	25	180	4,500
CBER (21 U.S.C. 513(f)(2)(ii))	1	1	1	180	180
Total					7,280

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. Based on FDA's experience with the de novo classification program, FDA expects the program to continue to be utilized as a viable program in the future. It is expected that the number of de novos will increase over its current rate and reach a steady rate of approximately 50 submissions per year.

FDA estimates from past experience with the de novo petition program that the complete process involved with the program under section 513(f)(2)(i) of the FD&C Act takes approximately 100 hours. FDA estimates from past experience with the de novo petition program that the complete process involved with the program under section 513(f)(2)(i)(ii) FD&C Act takes approximately 180 hours. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a de novo petition (and related materials), have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted. Therefore, the total reporting burden hours is estimated to be 7,280 hours.

This draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910-0120.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-19253 Filed 08/13/2014 at 8:45 am; Publication Date: 08/14/2014]